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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,873	09/05/2003	Michael S. Kopreski	00-1312-K	5207

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EXAMINER

LU, FRANK WEI MIN

ART UNIT PAPER NUMBER

1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/658,873

Applicant(s)

KOPRESKI, MICHAEL S.

Examiner

Frank W. Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14, 16-23, 25, 27-38 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) 3, 7, 10, 11, 19, 21, 22, 30, 33-38, 49 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32 and 45-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on January 23, 2007 has been entered. The claims pending in this application are claims 1-12, 14, 16-23, 25, 27-38, and 45-50 wherein claims 3, 7, 10, 11, 19, 21, 22, 30, 33-38, 49, and 50 have been withdrawn due to restriction requirement and species election. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response filed on January 23, 2007. Therefore, claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 will be examined.

Election/Restrictions

2. This application contains claims 35-38 drawn to an invention nonelected filed on May 31, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

3. Claim 9 is objected to because of the following informality: "one or a plurality of an RNA species" in lines 5 and 6 should be ""one or a plurality of RNA species".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Scope of enablement

Claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting a product amplified from total extracellular RNA from plasma or serum of a human or an animal, does not reasonably provide enablement for detecting, inferring, or monitoring any kind of disease or any kind of cancer or premalignancy in a human or animal using the methods recited in claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 45, and 46 and evaluating a human or an animal for any kind of disease such as any kind of cancer or premalignancy using the methods recited in claims 31, 32, 47, and 48. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

The nature of the invention

The claims are drawn to a method of detecting, inferring or monitoring a neoplastic disease in a human, a method to detect, infer or monitor a disease in a human, and a method for evaluating a human for a neoplastic disease. The invention is an class of invention which the

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CAFC has characterized as “the unpredictable arts such as chemistry and biology.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The Breadth of The Claims

Claims 1, 2, 4-6, 8, 20, 23, 25, 27-29, 45, and 46 encompass a method of detecting, inferring or monitoring any kind of neoplastic disease in a human by detecting any kind of RNA that expressed or overexpressed in a neoplastic disease in plasma or serum or a non-cellular fraction of blood. Claims 9, 12, 14, and 16-18 encompass a method of detecting, inferring or monitoring any kind of disease in a human by comparing the amount or concentration or comparative value of total extracellular RNA or one or a plurality of an RNA species in plasma or serum to a reference range RNA amount, concentration, or value determined from a defined group or population. Claims 31, 32, 47, and 48 encompass a method for evaluating a human for a neoplastic disease by determining an amount or concentration of any kind of housekeeping gene RNA in the presence or absence of tumor-associated RNA in blood plasma or serum or non-cellular fraction of blood.

Working Examples

The specification provides working examples (see pages 24-26) for detecting tyrosinase RNA in serum from normal human and a human with malignant melanoma and for detecting c-abl RNA in serum from human.

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The Amount of Direction or Guidance Provided and The State of The Prior Art

Although the specification teaches to detect tyrosinase RNA in serum from normal human and a human with malignant melanoma and detect c-abl RNA in serum from human (see the specification, pages 24-26), the specification does not provide a guidance to show that: (1) detection of any kind of RNA that expressed or overexpressed in a neoplastic disease in plasma or serum or a non-cellular fraction of blood can be used for detecting, inferring or monitoring any kind of neoplastic disease in a human; (2) comparison of the amount or concentration or comparative value of total extracellular RNA or one or a plurality of an RNA species in plasma or serum with a reference range RNA amount, concentration, or value determined from a defined group or population can be used for detecting, inferring or monitoring any kind of disease in a human; and (3) determination of an amount or concentration of any kind of housekeeping gene RNA in the presence or absence of tumor-associated RNA in blood plasma or serum or non-cellular fraction of blood can be used for evaluating a human for a neoplastic disease. Furthermore, there is no experimental data in the specification to support the claimed invention. During the process of the prior art search, the examiner has not found any prior art which is related to claimed invention.

Level of Skill in The Art, The Unpredictability of The Art, and The Quantity of Experimentation Necessary

While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether: (1) detection of any kind of RNA that expressed or overexpressed in a neoplastic disease in plasma or serum or a non-cellular fraction of blood

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can be used for detecting, inferring or monitoring any kind of neoplastic disease in a human; (2) comparison of the amount or concentration or comparative value of total extracellular RNA or one or a plurality of an RNA species in plasma or serum with a reference range RNA amount, concentration, or value determined from a defined group or population can be used for detecting, inferring or monitoring any kind of disease in a human; and (3) determination of an amount or concentration of any kind of housekeeping gene RNA in the presence or absence of tumor-associated RNA in blood plasma or serum or non-cellular fraction of blood can be used for evaluating a human for a neoplastic disease. Furthermore, there is no experimental data in the specification to support the claimed invention. First, since the phrase “the amplified product or signal of one or more RNA or cDNA therefrom is detected in an amount or concentration not less than the reference amount or concentration for said RNA or cDNA therefrom determined from a human group or population with said neoplastic disease” recited in claims 1 and 5 can be read as that the amplified product or signal of one or more RNA or cDNA therefrom is detected in an amount or concentration that is equal to the reference amount or concentration for said RNA or cDNA therefrom determined from a human group or population with said neoplastic disease, it is unclear how to detect, infer or monitor a neoplastic disease in a human when the amplified product or signal of one or more RNA which is /are expressed or overexpressed in the neoplastic disease or cDNA therefrom is detected in an amount or concentration that is equal to the reference amount or concentration for said RNA or cDNA therefrom determined from a human group or population with said neoplastic disease. Second, since total extracellular RNA in plasma or serum is a RNA mixture which contains a lot of different RNAs, it is unclear how to detect, infer or monitor any kind of disease in a human by comparing the amount or

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concentration or comparative value of total extracellular RNA or one or a plurality of an RNA species in plasma or serum with a reference range RNA amount, concentration, or value determined from a defined group or population. Third, since claims 31 and 32 do not require that the housekeeping gene is a specific housekeeping gene and it is known that some of housekeeping genes do not correlated with cancers (see Table 2 in page 742 and 743 from BioTechniques, 38, 739-745, 2005), it is unclear how to evaluate a human for a neoplastic disease by determining an amount or concentration of any kind of housekeeping gene RNA in the presence or absence of tumor-associated RNA in blood plasma or serum or non-cellular fraction of blood. With above unpredictable factor, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. The undue experimentation at least includes to test whether the methods recited in claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 45, and 46 can be used for detecting, inferring, or monitoring any kind of disease or any kind of cancer or premalignancy in a human or animal using and the methods recited in claims 31, 32, 47, and 48 can be used for evaluating a human or an animal for any kind of disease such as any kind of cancer or premalignancy.

Conclusion

In the instant case, as discussed above, the level of unpredictability in the art is high, the specification provides one with no guidance that leads one to claimed methods. One of skill in the art cannot readily anticipate the effect of a change within the subject matter to which the claimed invention pertains. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of

any working examples and the no teaching in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Response to Arguments

In page 12, third and fourth paragraphs of applicant's remarks, applicant argues that "[A]pplicants respectfully contend that were the first to provide evidence that disease-associated RNA could be detected in blood in humans with neoplastic disease, and that they are entitled to the claimed scope since the skilled worker would not have to exercise undue experimentation in view of their disclosure".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, since the phrase "the amplified product or signal of one or more RNA or cDNA therefrom is detected in an amount or concentration not less than the reference amount or concentration for said RNA or cDNA therefrom determined from a human group or population with said neoplastic disease" recited in claims 1 and 5 can be read as that the amplified product or signal of one or more RNA or cDNA therefrom is detected in an amount or concentration that is equal to the reference amount or concentration for said RNA or cDNA therefrom determined from a human group or population with said neoplastic disease, it is unclear how to detect, infer or monitor a neoplastic disease in a human when the amplified product or signal of one or more RNA which is /are expressed or overexpressed in the neoplastic disease or cDNA therefrom is detected in an amount or concentration that is equal to the reference amount or concentration for said RNA or cDNA therefrom determined from a human group or population with said neoplastic disease. Second, since total extracellular RNA in plasma or serum is a RNA mixture

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which contains a lot of different RNAs, it is unclear how to detect, infer or monitor any kind of disease in a human by comparing the amount or concentration or comparative value of total extracellular RNA or one or a plurality of an RNA species in plasma or serum with a reference range RNA amount, concentration, or value determined from a defined group or population.

Third, since claims 31 and 32 do not require that the housekeeping is a specific housekeeping gene and it is known that some of housekeeping genes do not correlated with cancers (see Table 2 in page 742 and 743 from BioTechniques, 38, 739-745, 2005), it is unclear how to evaluate a human for a neoplastic disease by determining an amount or concentration of any kind of housekeeping gene RNA in the presence or absence of tumor-associated RNA in blood plasma or serum or non-cellular fraction of blood. With above unpredictable factor, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 45, and 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 or 5 recites the limitation "the reference" in step c) of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no word "reference" in steps a) and b). Please clarify.

9. Claim 9 is rejected as vague and indefinite. Since the claim does not limit that a defined group or population is from a human or animal, it is unclear how to detect, infer or monitor a

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disease in a human or animal by comparing the amount or concentration or comparative value of total extracellular RNA or one or a plurality of an RNA species to a reference range RNA amount, concentration, or value determined from a species which is not a human or animal. Furthermore, although claim 9 is directed to a method to detect, infer or monitor a disease in a human or animal, the claim does not indicate how value of total extracellular RNA or one or a plurality of an RNA species is correlated to a disease as recited in claims 1 and 5. Please clarify.

Response to Arguments

In page 12, last paragraph of applicant's remarks, applicant argues that "[C]laims 9 and 20 have been amended to recite that they are directed to human disease and detecting RNA expression from human blood plasma or serum".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because applicant does not amend claim 9 as he argued.

10. Claim 9 is rejected as vague and indefinite because it is unclear how to detect, infer, or monitor a disease in a human using one or a plurality of an RNA species in a portion of plasma or serum from the animal. Please clarify.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

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is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,329,179 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 in this instant application are not identical to claims

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1-24 of U.S. Patent No. 6,329,179 B1, claims 1-24 of U.S. Patent No. 6,329,179 B1 are directed to the same subject matter and fall entirely within the scope of claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 in this instant application. In other words, claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 in this instant application are anticipated by claims 1-24 of U.S. Patent No. 6,329,179 B1.

13. Claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,759,217 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 in this instant application are not identical to claims 1-22 of U.S. Patent No. 6,759,217 B2, claims 1-22 of U.S. Patent No. 6,759,217 B2 are directed to the same subject matter and fall entirely within the scope of claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 in this instant application. In other words, claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 in this instant application are anticipated by claims 1-22 of U.S. Patent No. 6,759,217 B2.

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14. Claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6,916,634 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 in this instant application are not identical to claims 1-39 of U.S. Patent No. 6,916,634 B2, 1-39 of U.S. Patent No. 6,916,634 B2 are directed to the same subject matter and fall entirely within the scope of claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 in this instant application. In other words, claims 1, 2, 4-6, 8, 9, 12, 14, 16-18, 20, 23, 25, 27-29, 31, 32, and 45-48 in this instant application are anticipated by claims 1-39 of U.S. Patent No. 6,916,634 B2.

Response to Arguments

In page 13, last paragraph of applicant's remarks, applicant argues that "[A]pplicant will file a Terminal Disclaimer to overcome this ground of rejection upon withdrawal of the remaining grounds of rejection and when the pending claims are otherwise in condition for allowance".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because applicant does not file a terminal disclaimer.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

16. No claim is allowed.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

March 30, 2007

A handwritten signature in black ink, appearing to read 'Frank Lu', is positioned above the printed name.

FRANK LU
PRIMARY EXAMINER